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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,797	02/11/2004	Gregory Grabowski		4885

7590 11/15/2006  
FROST BROWN TODD LLC  
2200 PNC Center  
201 E. Fifth Street  
Cincinnati, OH 45202-4182

EXAMINER

RAGHU, GANAPATHIRAM

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/776,797	<b>Applicant(s)</b> GRABOWSKI ET AL.	
	<b>Examiner</b> Ganapathirama Raghu	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 37-65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 37-65 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Claims 37-65 are pending in this application.

#### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 37-50, drawn to a composition comprising a safe and effective amount of lipid hydrolyzing protein or polypeptide and a pharmaceutically acceptable carrier, classified in class 435, subclass 198.
- II. Claims 51-61, drawn to method of providing biologically active lipid hydrolyzing protein or polypeptide or mixtures thereof, to cells of a mammal having deficiency in biologically active lipid hydrolyzing protein or polypeptide, said method comprising administration into cells a vector comprising and expressing a DNA sequence encoding biologically active lipid hydrolyzing protein or polypeptide and expressing the DNA sequence in said cells to produce biologically active lipid hydrolyzing protein or polypeptide, classified in class 514, subclass 44.
- III. Claims 62-63, drawn to method of providing biologically active lysosomal acid lipase to cells of a mammal with atherosclerosis, comprising administration into cells a vector comprising and expressing a DNA sequence encoding lysosomal acid lipase, classified in class 514, subclass 44.
- IV. Claim 64, drawn to a method of treatment for Wolman's disease in a mammal comprising administering to said mammal a safe and effective amount of

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lysosomal acid lipase sufficient to treat the condition, classified in class 424, subclass 94.3.

- V. Claim 65, drawn to a method of treatment for Cholesteryl Ester Storage disease in a mammal comprising administering to said mammal a safe and effective amount of lysosomal acid lipase sufficient to treat the condition, classified in class 424, subclass 94.3.

The inventions are distinct, each from the other because of the following reasons:

Invention I is drawn to a product and is patentably distinct.

Inventions II-V are drawn to methods and process of use and are patentably distinct. Each of the methods or processes has different steps, using different components and modes of operation with different end results. They do not require each other for practice; have separate utilities. For example, the drawn to method of providing biologically active lipid hydrolyzing protein or polypeptide or mixtures thereof, to cells of a mammal having deficiency in biologically active lipid hydrolyzing protein or polypeptide, said method comprising administration into cells a vector comprising and expressing a DNA sequence encoding biologically active lipid hydrolyzing protein or polypeptide in groups II and III and the methods of treatment for Wolman's disease and Cholesteryl Ester Storage disease in a mammal comprising administering to said mammal a safe and effective amount of lysosomal acid lipase in groups IV-V, involve different and distinct steps and modes of operation and different disease conditions. The methods require different kinds of preparation and mode of use and are subject to separate manufacture and sale.

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Inventions I and IV-V are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the composition of group I can be used as an antigen to raise antibodies as opposed to its use in the methods of groups IV-V to treat disease conditions.

Inventions I and methods II-III are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the composition of group I is neither used nor made in the methods of groups II-III. They are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

***Rejoinder of restricted inventions***

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitation of

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the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. 821.04. Process claims that depend from or otherwise include all the limitation of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after allowance are governed by 37 C.F.R. 1.312.

In the event of a rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. thus, to be allowable, the rejoined claims must meet the criteria for patentability including the requirements of 35 U.S.C. 101; 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. 103(b), 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that process claims should be amended during prosecution either to maintain dependency on the product claims or otherwise include the limitation of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. 804.01.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533.

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The examiner can normally be reached on 8 am-4.30 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ganapathirama Raghu, Ph.D.  
Patent Examiner  
Art Unit 1652

  
**TEKCHAND SAIDHA**  
**PRIMARY EXAMINER**

Oct. 29, 2006.